Public Health Service

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751

d18976

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-98-59

June 25, 1998

Victor R. Tarin, President
Tarmac Products, Inc.
13295 N.W. 107th Avenue
Hialeah Gardens, Florida 33016

Dear Mr. Tarin:

During an inspection of your facility located at 13295 N.W. 107th Avenue, Hialeah Gardens, Florida 33016 on February 7-24, 1997, Investigator Stephen J. Tunks determined that you manufacture and repack various OTC and prescription human drug products within the meaning of section 201(g)(1)(b) of the Federal Food, Drug, and Cosmetic Act (the Act). The investigator documented significant deviations from the Current Good Manufacturing Practice (CGMP) Regulations for drugs [Title 21, Code of Federal Regulations, Parts 210 and 211 (21 CFR 210 and 211). These violations cause products manufactured by your firm to be adulterated within the meaning of section 501(a)(2)(B) of the Act as follows:

- Inadequate and insufficient stability data and no written stability program;
- Incomplete and inadequate master and batch records;
- Logs covering cleaning/maintenance of equipment are not maintained, nor has the cleaning procedure been validated;
- No validation or auditing of manufacturer's certificate of analysis for repacked products; and,
- Lack of tamper resistant labeling on your products (Adelgadina Tablets and Hemorrrodil Suppositories).

At the conclusion of the inspection, a List of Observations (FDA 483) including the above mentioned deficiencies was left with you.

For your information, the products, Sanafitil Ointment, Liquid and Powder, which contain undecylenic acid and are offered for the treatment of jock itch, as well as athlete's foot, are subject to the requirements of 21 CFR 333.250(c). The labeled warning statement should read "... if there is no improvement in 2 weeks ..." instead of 4 weeks, as the present label reads.

The above identification of violations is not intended to be an all inclusive list at your facility. It is your responsibility to ensure that all drug products are in compliance with the Act, and with GMP regulations. You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action. Other Federal agencies are routinely advised of Warning Letters issued so that they may take this information into account when considering the awards of contracts.

In order to facilitate the FDA in making the determination that such corrections have been made and thereby enabling FDA to withdraw its advisory to other Federal agencies concerning the award of government contracts, we request that you notify this office when corrective actions are completed.

Your should notify this office in writing, within fifteen (15) working days of receipt of this letter, of specific steps you have taken to correct these violations. If corrections cannot be completed within fifteen (15) working days, state the reason for the delay, and the time frame within which corrections will be completed.

You response should be directed to Martin E. Katz, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Ste. 200, Maitland, Florida 32751, telephone no. (407) 475-4729.

Sincerely,

Douglas D. Tolen
Director
Florida District